UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

DANIEL BOURBIA, individually and on behalf of all others similarly situated, Plaintiff, vs. S.C. JOHNSON & SON, INC., Defendant.	Civil Action No. 18-cv-03944 Hon. Paul A. Crotty

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT'S MOTION FOR RECONSIDERATION OF THIS COURT'S MARCH 21, 2019 OPINION AND ORDER

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

PRELIMINARY STATEMENT

Defendant S.C. Johnson & Son, Inc. ("SC Johnson" or "Defendant") submits this memorandum of law in support of its motion for reconsideration with respect to this Court's Opinion and Order of March 21, 2019 (the "Opinion and Order"), denying Defendant's motion to dismiss. There, this Court noted that the Environmental Protection Agency ("EPA") had approved the following efficacy statements for the label of SC Johnson's Off! FamilyCare Clean Feel Insect Repellent II product (the "Off! Product" or "Product"), after finding that the efficacy data submitted by SC Johnson supported the Product's repellency claims and instructions for use: "Effective protection from mosquitoes, biting flies and fleas"; "Repels insects for up to 3 to 4 hours." (Opinion and Order at 3.) This Court further noted that SC Johnson could not unilaterally change the label of the Off! Product, but could sell it only with the approved label unless and until the EPA approved a label amendment. (Opinion and Order at 9.) SC Johnson argued that, under the doctrine of preemption as developed by a series of Supreme Court decisions, state law liability for label language approved by the relevant federal agency was barred on the basis of both express preemption and conflict preemption.

Regarding conflict preemption, this Court correctly stated that the doctrine defeats state law claims "where it is 'impossible for a private party to comply with both state and federal requirements.'" Opinion and Order at 9 n.3 (quoting *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 473 (2013)). That means, as the Supreme Court held in *Mutual Pharmaceutical*, that plaintiffs cannot maintain state law causes of action challenging federally-approved label claims that could not be unilaterally amended, such as the efficacy claims on the Off! Product label here. But this Court concluded, citing *Cipollone v. Liggett*, 505 U.S. 504 (1992), that "[c]onflict preemption is

foreclosed here . . ., since Congress enacted a provision defining the preemptive reach of [the Federal Insecticide, Fungicide, and Rodenticide Act ('FIFRA').]" (Opinion and Order at 9 n.3.)

Defendant respectfully submits that this conclusion is incorrect, and that this Court's interpretation of *Cipollone* has been rejected by the Supreme Court. *See, e.g.*, *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995) ("According to respondents and the Court of Appeals, [*Cipollone*] held that implied pre-emption cannot exist when Congress has chosen to include an express pre-emption clause in a statute. This argument is without merit."). In other words, claims barred by conflict preemption remain barred on that basis without regard to the existence of an express preemption provision in the relevant federal statute. SC Johnson thus respectfully seeks reconsideration of this Court's Opinion and Order and requests that, on reconsideration, the Court dismiss all claims on that basis.[1]

ARGUMENT

I. Standard for Motion for Reconsideration

Motions for reconsideration are governed by Local Civil Rule 6.3. A district court "has broad discretion in determining whether to grant a motion [for reconsideration]." *Simon v. City of New York*, No. 14-cv-8391, 2015 WL 4092389, at *1 (S.D.N.Y. Jul. 6, 2015) (quoting *Baker v. Dorfman*, 239 F.3d 415, 427 (2d Cir. 2000). Such a motion is appropriate where "the moving party can point to controlling decisions or data that the court overlooked—matters, in other

[1] While SC Johnson disagrees with the Court's analysis under the express preemption doctrine, including its application of *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), SC Johnson is not seeking reconsideration with respect to that doctrine and authority, which the Court addressed. SC Johnson will undertake a more vigorous analysis of the express preemption defense on a fuller record in the event it proves necessary. Defendant seeks reconsideration instead of the conflict analysis of *Mutual Pharmaceutical* and *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), which together provide controlling authority demonstrating that Plaintiff's challenges to the Off! Product label here are preempted.

words, that might reasonably be expected to alter the conclusion reached by the court." *Medisim Ltd. v. BestMed LLC*, No. 10-cv-2463, 2012 WL 1450420, at *1 (S.D.N.Y. Apr. 23, 2012) (internal quotation marks omitted). A motion for reconsideration may also be granted to "correct a clear error or prevent manifest injustice." *Id.*

II. Conflict Preemption is Not Foreclosed by the Existence of an Express Preemption Provision in FIFRA

In its March 21, 2019 Opinion and Order, this Court, quoting *Mutual Pharmaceutical*, correctly noted that state law is "impliedly pre-empted where it is impossible for a private party to comply with both state and federal requirements." (Opinion and Order at 9 n.3.) Nevertheless, citing *Cipollone*, this Court found that "[c]onflict preemption is foreclosed here . . ., since Congress enacted a provision defining the preemptive reach of FIFRA." (*Id.*) As further discussed below, this interpretation of *Cipollone*—*i.e.*, that conflict preemption is foreclosed where Congress has chosen to include an express preemption provision in the relevant federal statute—has been squarely rejected by the Supreme Court.

A. *Cipollone* Did Not Hold That Conflict Preemption is Foreclosed Where Congress Has Enacted an Express Preemption Provision.

In *Freightliner Corp.*, the Supreme Court considered whether the National Traffic and Motor Vehicle Safety Act (the "Safety Act") expressly or impliedly preempted plaintiff's common-law design defect claims against truck manufacturers. Respondents had argued, and the Court of Appeals had found, that *Cipollone* held that implied preemption could not exist where Congress had chosen to include an express preemption clause in a relevant statute. The *Freightliner* Court found that argument to be "without merit," explaining that *Cipollone* had not announced "a categorical rule precluding the coexistence of express and implied pre-emption[.]" *Id.* at 288.

Subsequently, in *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861 (2000), the Court found that plaintiff's common law tort action alleging that an automobile manufacturer was negligent in failing to equip plaintiff's automobile with a driver's side airbag was preempted because it "actually conflicted" with a Department of Transportation standard promulgated under the federal statute at issue, the Safety Act, which required automobile manufacturers to equip some but not all of their 1987 vehicles with passive restraints. The Safety Act's express preemption provision provided:

> Whenever a Federal motor vehicle safety standard established under this subchapter is in effect, no State . . . shall have any authority either to establish, or to continue in effect, with respect to any motor vehicle or item of motor vehicle equipment any safety standard applicable to the same aspect of performance of such vehicle or item of equipment which is not identical to the Federal standard. Nothing in this section shall be construed as preventing any State from enforcing any safety standard which is identical to a Federal safety standard.

15 U.S.C. § 1392(d). The Safety Act also contained a saving clause, which stated: "Compliance with any Federal motor vehicle safety standard issued under this subchapter does not exempt any person from any liability under common law." *Id.* § 1397(k).

The *Geier* Court held that the Safety Act's express preemption provision did not expressly preempt plaintiff's common law tort action, since the presence of the saving clause required that the preemption provision be read narrowly to preempt only state statutes and regulations. 529 U.S. at 868. However, the Court explained that the saving clause (like the express preemption provision) did *not* bar the ordinary working of conflict preemption principles:

> Nothing in the language of the saving clause suggests an intent to save state-law tort actions that conflict with federal regulations. The words "[c]ompliance" and "does not exempt" sound as if they simply bar a special kind of defense, namely, a defense that compliance with a federal standard automatically exempts a defendant from state law, whether the Federal Government meant that standard to be an absolute requirement or only a minimum one. [. . .]

> [W]e conclude that the saving clause foresees—it does not foreclose—the possibility that a federal safety standard will pre-empt a state common-law tort action with which it conflicts.

Id. at 869-70 (internal citations omitted). The Court further explained:

> Neither do we believe that the pre-emption provision, the saving provision, or both together, create some kind of "special burden" beyond that inherent in ordinary pre-emption principles—which "special burden" would specially disfavor pre-emption here. The two provisions, read together, reflect a neutral policy, not a specially favorable or unfavorable policy, toward the application of ordinary conflict pre-emption principles. [. . .]
>
> Why, in any event, would Congress not have wanted ordinary pre-emption principles to apply where an actual conflict with a federal objective is at stake? Some such principle is needed. In its absence, state law could impose legal duties that would conflict directly with federal regulatory mandates, say, by premising liability upon the presence of the very windshield retention requirements that federal law requires. Insofar as petitioners' argument would permit common-law actions that "actually conflict" with federal regulations, it would take from those who would enforce a federal law the very ability to achieve the law's congressionally mandated objectives that the Constitution, through the operation of ordinary pre-emption principles, seeks to protect.

Id. at 871-72 (internal citations omitted).

More recently, in *Arizona v. United States*, 567 U.S. 387 (2012), the Supreme Court again confirmed the fact that conflict preemption principles are not displaced by the presence of an express preemption provision. Citing *Geier*, the Court stated that "the existence of an 'express preemption provisio[n] does *not* bar the ordinary working of conflict preemption principles' or impose a 'special burden' that would make it more difficult to establish the preemption of laws falling outside the clause." 567 U.S. at 406 (emphasis in original). In other words, claims barred by conflict preemption remain barred on that basis without regard to the existence of an express preemption provision.

B. Plaintiff's Claims are Barred by Conflict Preemption Because They Render it Impossible for SC Johnson to Comply with Both State and Federal Requirements.

As this Court stated in its March 21, 2019 Opinion and Order, the conflict preemption doctrine defeats state law claims "where it is 'impossible for a private party to comply with both state and federal requirements.'" Opinion and Order at 9 n.3 (quoting *Mut. Pharm. Co.*, 570 U.S. at 473). As the Second Circuit recently explained, citing *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), "[w]here federal and state law conflict—that is, where it is impossible for a party to follow both federal and state law—state law must give way." *Gibbons v. Bristol-Myers Squibb Co*., 2019 WL 1339013, at *6 (2d Cir. Mar. 26, 2019). That means, as the Supreme Court held in *Mutual Pharmaceutical*, that plaintiffs cannot maintain state law causes of action challenging a federally-approved label that could not be unilaterally amended, such as the Off! Product label here. The Court's Opinion and Order expressly found conflict between the EPA-approved Product label (and its efficacy claims) and Plaintiff's state-law claims against the label claims: "Once a manufacturer registers a pesticide with the EPA, the manufacturer generally may not modify the label without approval." (Opinion and Order at 2.) Accordingly, the Court's own Opinion and Order supports conflict preemption.

The contours of conflict preemption were sharply defined by the Supreme Court in three post-*Bates* decisions applying Food and Drug Administration ("FDA") regulations on labeling: *Mutual Pharmaceutical*, *PLIVA*, and *Wyeth v. Levine*, 555 U.S. 555 (2009). In *Wyeth*, the Supreme Court found that a failure to warn claim was not preempted by federal law under conflict preemption because the federal regulation in that case—called a "changes being effected" or CBE regulation—permitted the brand-name drug company to make unilateral revisions to its label. The right of unilateral action meant that Wyeth could have made the revisions that plaintiff alleged were required by state law without violating FDA regulations.

The Court held: "Wyeth has failed to demonstrate that it was impossible for it to comply with both federal and state requirements. The CBE regulation permitted Wyeth to unilaterally strengthen its warning . . . ." 555 U.S. at 573.

In contrast, FDA regulations do not permit a *generic* drug company to unilaterally change its label, and that led to a significantly different result in both *Mutual Pharmaceutical* and *PLIVA*, where the Supreme Court held that state law claims (such as failure to warn) against generic drug manufacturers were preempted. In that regard, Justice Thomas, writing for the majority, assumed that generic drug manufacturers might seek assistance from the FDA in obtaining a new label upon learning of new risks not adequately addressed in the approved label. But the state law claims were preempted *whether or not* the defendants made any requests to the FDA:

> The federal duty to ask the FDA for help in strengthening the corresponding brand-name label, assuming such a duty exists, does not change this analysis. Although requesting FDA assistance would have satisfied the Manufacturers' federal duty, it would not have satisfied their state tort-law duty to provide adequate labeling. State law demanded a safer label; it did not instruct the Manufacturers to communicate with the FDA about the possibility of a safer label. [. . .]
>
> *The question for "impossibility" is whether the private party could independently do under federal law what state law requires of it*. *See Wyeth*, 555 U. S. at 573 (finding no pre-emption where the defendant could "unilaterally" do what state law required).

PLIVA, 564 U.S. at 619-20 (emphasis added). As the Court further explained, state law claims were not preempted in *Wyeth* because "the CBE regulation, 21 CFR § 314.70(c)(6)(iii), permitted a brand-name drug manufacturer like Wyeth 'to unilaterally strengthen its warning' without prior FDA approval." *Id.* at 624.

There is no CBE regulation under FIFRA, and the EPA does not permit regulated entities to make unilateral changes to EPA-approved labels.[2] For conflict preemption purposes, SC Johnson is in the same position as the generic drug companies in *Mutual Pharmaceutical* and *PLIVA*. In its Opinion and Order, this Court held that "[a] pesticide manufacturer cannot escape liability for violations of FIFRA and state law just because it cannot unilaterally strengthen its labels without EPA approval." (Opinion and Order at 9.) However, not only can SC Johnson not unilaterally *strengthen* the EPA-approved Off! Product label, it cannot make any changes *at all* to the efficacy claims on the label unless and until the EPA approves those changes. In other words, SC Johnson has a federal-law duty not to alter the Off! Product's EPA-approved label unless and until such changes are submitted to, reviewed by, and approved by the EPA. As the Court noted in *Mutual Pharmaceutical*, "In the instant case, it was impossible for Mutual to comply with both its state-law duty to strengthen the warnings on sulindac's label and its federal-law duty not to alter sulindac's label. Accordingly, the state law is pre-empted." 570 U.S. at 480.

Further, even assuming *arguendo* that SC Johnson has a federal duty to ask the EPA for assistance in changing the efficacy claims on the Product's label, state law actions challenging those same efficacy claims are preempted *whether or not* SC Johnson makes any such requests to the EPA, because "[t]he question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *PLIVA*, 564 U.S. at 620. As the *PLIVA* Court explained:

---

[2] FIFRA also declares it unlawful for any person to distribute or sell "any registered pesticide if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration under [FIFRA]." 7 U.S.C. § 136j(a)(1)(B).

> Before the Manufacturers could satisfy state law, the FDA—a federal agency—had to undertake special effort permitting them to do so. *To decide these cases, it is enough to hold that when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes.* Here, state law imposed a duty on the Manufacturers to take a certain action, and federal law barred them from taking that action. The only action the Manufacturers could independently take—asking for the FDA's help—is not a matter of state-law concern. [Plaintiffs'] tort claims are pre-empted.

Id. at 623-24 (emphasis supplied). Here, no less than in *PLIVA*, the Defendant cannot "independently satisfy" the alleged "state duties for pre-emption purposes," because it cannot amend the label claims at issue "without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency." And as the above passage from *PLIVA* makes clear, the Supreme Court's analysis is not limited to the FDA, but applies to the FDA only because it is a federal agency—that is, the preemption analysis flows not from the federal agency being the FDA, but from the FDA being a federal agency.

C. Nothing in *Bates* Forecloses Application of Ordinary Preemption Rules or of Later Supreme Court Preemption Decisions.

Like any other Supreme Court decision analyzing the scope and extent of preemption, *Bates* must be read not in isolation, but in light of later decisions, especially those (such as *Mutual Pharmaceutical*) that explicitly cite, interpret, and apply *Bates*. *See, e.g.*, *Gibbons*, 2019 WL 1339013 at *6 (noting that, following the Supreme Court decisions in *Wyeth*, *PLIVA*, and *Mutual Pharmaceutical*, the Courts of Appeals have "synthesized requirements" of preemption with respect to failure-to-warn claims). Three core principles of preemption can be synthesized from the prevailing case law. First, federal requirements include both (1) federal statutes and regulations and (2) labeling imposed by the regulating federal agency where the laws require agency premarket review and approval of efficacy data as a condition of registration. Second, state law requirements include both (1) state statutes and regulations and (2) lawsuits seeking to

impose liability on the basis of the product label. Third, the federal requirements and state law requirements conflict irreconcilably where the defendant cannot unilaterally alter the label to conform to the standard set forth by the state law challenge, preempting such state law challenge.

As this Court noted in its March 21, 2019 Opinion and Order, the prohibitions in FIFRA's express preemption provision, 7 U.S.C. § 136v(b), apply only to "requirements" for labeling or packaging. Opinion and Order at 6-7 (quoting *Bates*, 544 U.S. at 443, 452). The Supreme Court had no cause to consider in *Bates* whether the only language on the label that was directly at issue—the express warranty—itself imposed a federal requirement, because such express warranty language was not part of any federal agency review and approval process.[3] Furthermore, *Bates* did not address the need for EPA approval for altering any label language because the defense in that case was simply that petitioners' state law claims could lead to a jury verdict that could induce the manufacturer to change its label, and the Court held that such inducements were not determinative of whether a state law rule constituted a new labeling "requirement." *See Bates*, 544 U.S. at 443-45 ("An occurrence that merely motivates an optional decision does not qualify as a requirement.").[4]

---

[3] As further explained below, *Riegel*, *Wyeth, PLIVA*, and *Mutual Pharmaceutical* all make plain that a federally-imposed premarket review and approval process gives rise to federal requirements in the form of the approved label.

[4] Where the state law claim seeks to impose liability based on the label claim itself, the state law claim is not a mere state law "inducement" to alter label language but a state law "requirement" for labeling or packaging, as the Court made clear in *Mutual Pharmaceutical.* The Court rejected the argument, advanced by the dissent, that New Hampshire law "'merely create[s] an incentive' to alter sulindac's label or composition …, but does not impose any actual 'legal obligation.'" *Mut. Pharm. Co.,* 570 U.S. at 490-91 (citations omitted). Duties imposed by tort law are no less requirements than duties imposed by statutory law. Significantly, the Court also rejected the notion that *Bates* was "to the contrary":

> The dissent is correct that *Bates* held a Texas state-law design-defect claim not to be pre-empted. But, it did so because the design-defect claim in question was not a

In *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), the Court—interpreting the express preemption provision of the Medical Device Amendments ("MDA") to the FDCA, which contains language substantially similar to FIFRA § 136v(b)—further clarified what constitutes federal "requirements" that preempt state law claims.[5] Under the MDA, the scope of federal oversight varies with the type of device at issue, just as the scope of federal oversight under FIFRA varies with the type of pesticide at issue. The most extensive oversight is reserved for devices that undergo the premarket approval process—these devices may enter the market only if the FDA reviews their design, labeling, and manufacturing specifications and determines that those specifications provide a reasonable assurance of safety and effectiveness. *Riegel*, 552 U.S. at 317-19. The premarket approval process includes review of the device's proposed labeling, including FDA evaluation of safety and effectiveness under the conditions of use set forth on the label and determination that the proposed labeling is neither false nor misleading. *Id.* at 318. Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in labeling or any other attribute that would affect safety or effectiveness. *Id.* at 319. If the applicant wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval. *Id.* *Riegel* described the issue before the Court as follows:

> "requirement '*for labeling or packaging*'" and thus fell outside the class of claims covered by the express pre-emption provision at issue in that case.

Mut. Pharm. Co., 570 U.S. at 491 (emphasis in original).

[5] The MDA preemption provision provides that a state shall not "establish or continue in effect with respect to a device intended for human use any requirement— (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a).

> Since the MDA expressly pre-empts only state requirements "different from, or in addition to, any requirement applicable . . . to the device" under federal law, § 360k(a)(1), we must determine whether the Federal Government has established requirements applicable to [defendant]'s catheter. If so, we must then determine whether the [plaintiffs'] common-law claims are based upon [state] requirements with respect to the device that are "different from, or in addition to," the federal ones, and that relate to safety and effectiveness. § 360k(a).

Id. at 321-22. The Court found that "[p]remarket approval … imposes 'requirements' under the MDA," *id.* at 322, because, *inter alia*, "the FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness" and "the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Id.* at 323.

Unlike the situation at issue in post-*Bates* preemption decisions such as *Riegel*, *Wyeth*, *Mutual Pharmaceutical*, and *PLIVA*, *Bates* did not address a label claim that was subject to a federal agency's premarketing review and approval process that creates a federal "requirement." In these post-*Bates* cases, the question arose whether the federal requirement was consistent with the state requirement—in *Wyeth*, there was potential consistency because the brand manufacturer had a unilateral right to amend the label (the federal requirement) in a manner that would conform to the state law claim; in *PLIVA*, *Mutual Pharmaceutical*, and *Riegel*, there was no such right of unilateral amendment to the federal requirement, and therefore the conflict entailed preemption.

As the Supreme Court emphasized in *Bates*, state law requirements must be "measured against any relevant EPA regulations that give content to FIFRA's misbranding standards." *Bates*, 544 U.S. at 453. EPA regulations state that the agency will register a pesticide only if it has determined that the product is *not* misbranded as that term is defined in FIFRA and that its labeling and packaging comply with the applicable requirements of FIFRA and its relevant

regulations. 40 CFR § 152.112(f); *see also Bates*, 544 U.S. at 454 ("[A] manufacturer should not be held liable under a state labeling requirement subject to § 136v(b) unless the manufacturer is also liable for misbranding as defined by FIFRA.").[6]

The only claim in *Bates* that directly addressed the label of the product at issue was the express warranty claim, which pertained to a voluntarily-assumed guarantee that the chemical compound matched the stated representations; the other claims were based on oral statements of sales agents. While those statements were said to be consistent with non-reviewed label statements regarding the efficacy of the product, the oral statements were not mandated by any regulation—and even to the extent the statements were consistent with label statements, such label statements were not subject to federal agency review, and therefore the oral statements consistent therewith did not communicate any federal requirement.[7] There was no cause for *Bates* to address the label amendment issue at all because the EPA did not engage in premarketing review, evaluation and approval of the claim at issue. *See Bates*, 544 U.S. at 440 ("This general waiver [of efficacy review] was in place at the time of Strongarm's registration;

---

[6] In *Bates*, an amendment to FIFRA permitted the EPA to waive agency review and determination of any efficacy claim of the agricultural pesticide at issue, and therefore no determination was made concerning whether the efficacy claims were adequately supported by data or instead caused the product to be misbranded. The instant case presents a different situation. Here, as a result of its review and approval of SC Johnson's efficacy data and the efficacy claims contained on the Off! Product's labeling, the EPA has already determined that the Product is not misbranded as that term is defined in FIFRA and that its labeling and packaging comply with the applicable requirements of FIFRA and its relevant regulations.

[7] Given that the claims in *Bates* did not directly challenge the label of the agricultural pesticide at issue, it remained an open issue after *Bates* whether any claim challenging a statement on a label was preempted—even where the label was not the subject of premarketing review and approval—apart from express warranties that were separate from labeled statements concerning the product. Many courts, such as the Fourth Department in *Esposito v. Contec, Inc.*, 147 A.D.3d 1384 (4th Dep't 2017), hold all challenges to labeling and packaging to be preempted. This Court need not decide that question because the premarketing review and approval process imposed federal requirements in the form of the efficacy claims at issue.

thus, *EPA never passed on the accuracy of the statement in Strongarm's original label* recommending the product's use 'in all areas where peanuts are grown.'") (emphasis added).

In contrast, the only claims here are based directly on labeled efficacy claims that are the product of the EPA's review, evaluation, and approval of the Off! Product's efficacy data. As the Supreme Court has made clear, and explicitly stated in *Riegel*, the federal agency premarketing review and approval process gives rise to federal requirements, and therefore a state law challenge to such federal requirements is preempted.

CONCLUSION

All of Plaintiff's claims are a direct attack on the core efficacy claims on the Off! Product label. As this Court observed in its March 21, 2019 Opinion and Order, the EPA specifically approved the label claims at issue upon determining that the efficacy data submitted by SC Johnson supported the label's repellency claims and instructions for use. (Opinion and Order at 3.) This Court further noted that, under federal law, SC Johnson could not unilaterally change the label of the Off! Product, but could sell it only with the approved label unless and until the EPA approved a label amendment. (Opinion and Order at 9.) The Court's findings compel dismissal under conflict preemption rules that apply even in the absence (or presence) of an express preemption provision: the state law requirements alleged by Plaintiff are in irreconcilable conflict with the federal requirements imposed by the EPA and its regulations.

For the foregoing reasons, Defendant respectfully requests reconsideration of this Court's March 21, 2019 Opinion and Order and requests that, on reconsideration, the Court dismiss all claims.

Dated: New York, New York
April 4, 2019

SIDLEY AUSTIN LLP

By: /s/ James D. Arden
James D. Arden (JA-8779)
787 Seventh Avenue
New York, New York 10019
(212) 839-5300
jarden@sidley.com

Attorneys for Defendant